Bayer HealthCare
Consumer Care Division

April 2, 2004

Catherine W. Fish, MS, RD
Senior Associate Director
Regulatory Affairs

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: Docket 77N-0094

Requested Public Feedback Meeting re: 12/8/03 Advisory Committee Hearing for Aspirin Primary Prevention Labeling: Clarification of Previously Submitted Information

Bayer HealthCare LLC
Consumer Care Division
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

Phone: (973) 254-4793
Fax: (973) 254-4875

Dear Dr. Ellenberg:

Bayer HealthCare appreciates your consideration of our meeting request to continue the dialogue regarding the safety and efficacy of aspirin in the primary prevention of myocardial infarction (MI). The December 8, 2003 Cardio-Renal Advisory Committee Hearing provided important perspective on the public health importance of the approval of this indication for aspirin, and highlighted a number of areas where discussion is warranted.

To facilitate the discussion, the attached document addresses the questions proposed in our meeting request of January 16, 2004; it is intended to serve as a roadmap for our meeting, providing data and perspective relevant to the benefits and risks of aspirin in the proposed indication. Most important, it is designed to elicit the Agency's views on a number of issues pertinent to the review of our Citizen's Petition. As you know, our objective is to seek common ground with respect to the proposed indication, as supported by the available evidence, to ensure appropriate aspirin use in patients at appropriate risk of MI.

In summary, Bayer's position on the key questions is as follows:

- Sufficient evidence exists to support the use of aspirin (75 – 325 mg) in individuals at moderate risk or greater of coronary heart disease (CHD) who have not experienced a previous MI.
- A shift from event-based to risk-based labeling (i.e., 10% risk or greater based on standard, available risk assessment tools (e.g. Framingham)), similar to that used in the labeling of statin drugs, will add needed clarity to healthcare professionals regarding appropriate use of aspirin for primary prevention.

77N-0094

SUP 47

- Since there is no biological difference between men and women in terms of the cardiovascular benefits of aspirin, and adequate numbers of women have been studied, as with secondary prevention, the use of aspirin for primary prevention is appropriate in both male and female, moderate-to-high risk individuals.
- Bayer shares the belief expressed by a majority of the Cardio-Renal Advisory Committee members that the existing body of data supports the use of aspirin in preventing first non-fatal MI, particularly in men, and that this was statistically significant in the key primary prevention studies.
- It is clear that the Committee recognized the public health importance of the Petition as reflected by their personal use and recommendation of aspirin for the proposed indication, but may require additional data for broader labeling beyond non-fatal MI.

As a follow up to the Advisory Committee hearing, we believe the questions submitted as part of our meeting request will allow us to gain a better understanding of the Agency's views on these issues, and will identify a path forward through expanded professional labeling that will help to address the immense public health need for better clarity in the labeling of aspirin. Improved clarity regarding the appropriate candidates for aspirin use can have significant impact in reducing the burden of MI.

Bayer appreciates the urgency the Agency has given this Petition. We acknowledge that it has been handled on an NDA timetable and has received high-level Agency involvement. We remain committed to helping the Agency appropriately access and evaluate the available evidence to ensure that the Agency's action on the Petition reflects accurately the totality of the evidence with respect to the safety and efficacy of aspirin. We are aware that the healthcare community, as well as patients, is interested in greater clarity regarding appropriate aspirin use and that our efforts together in this regard can have significant public health impact. To that end, it is important to ensure that whatever action the Agency ultimately takes does not discourage patients from following their physician's advice regarding aspirin use.

We encourage the Agency to take action at this time, as there is an urgent need to provide credible direction regarding appropriate aspirin use. The data are clear that a significant benefit can be achieved today through approval of aspirin therapy to reduce the risk of MI in moderate-risk individuals. While additional data might broaden the population that is appropriate for aspirin in the future, it does not negate the importance of the significant reductions in non-fatal MI demonstrated.

Thank you very much for the opportunity to solicit your views and move forward together in the interest of public health. Should you have any questions, please feel free to contact me at 973-254-4793.

Bayer HealthCare
Consumer Care Division

Catherine Fish
Senior Associate Director, Regulatory Affairs